K111079

MAY 13 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

Establishment:

- Address: Siemens AG, Medical Solutions
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  Germany
- Registration Number: 3002808157
- Contact Person: Sven Knoke
  Regulatory Affairs Manager
  Telephone: +49 (9131) 84-4687
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Device Name and Classification:

- Trade Name: *syngo*.via WebViewer
- Classification Name: Picture Archiving and Communications System
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

Date of submission: March 2011

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description and Intended Use:
This premarket notification covers Siemens' PACS *syngo*.via WebViewer.

syngo.via WebViewer is intended to be a software-only solution for reviewing medical images from *syngo.via*.
The system cannot be used as stand-alone device. It is intended to be an option for *syngo*.via system only.
syngo.via WebViewer is not intended for storage or distribution of medical images from one medical device to another.
syngo.via WebViewer is a client server architecture and the client is intended to run on web clients which are connected to the healthcare institution IT infrastructure where the customer has to ensure HIPPA compliance.
syngo.via WebViewer supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.
The communication of *syngo*.via WebViewer with connected medical IT systems will be done via standard interfaces such as but not limited to DICOM.
The system is not intended for the displaying of digital mammography images for diagnosis in the U.S

The system is a software only medical device. It defines minimum requirements to the hardware it runs on. The hardware itself is not seen as a medical device and not in the scope of this 510(k) submission.

It supports the physician in diagnosis and treatment planning.

syngo.via WebViewer Data Management

… ensures all authorized personnel fast and continuous access to radiological data. It's main functionality ranges from availability of images with regard to data security, open interfaces.

Integration:

The Workflow Management enables by integration of any HL7- / DICOM-compatible RIS (IHE Year 5) to the *syngo* product family consistent workflow within the healthcare organization.

Technological Characteristics:

syngo.via WebViewer server part is a "software only"-system, which will be delivered on CD-ROM / DVD to be installed on common IT hardware. This hardware has to fulfil the defined requirements. The Software will be installed by Siemens service engineers only.

The backend communication and storage solution is based on Windows 2008 operating system. The client machines are based on standard computer (Mac / Windows PC / Linux PC). The client application runs in a standard webbrowser - such as but not limited to Internet Explorer, Firefox, Safari – please refer to the specification for the complete list of supported web browsers.

Any hardware platform, which complies to the specified minimum hardware and software requirements and with successful installation verification and validation activities, can be supported.

The herewith described *syngo*.via WebViewer supports DICOM formatted images (CT, MR) and objects (SC, pdf).

The *syngo*.via WebViewer will be marketed as a software only solution for the end-user (with recommended hardware requirements). The server part will be installed by trained service engineers only. Any special needs such as integration in a specific environment and updates / upgrades will be covered by individual service contract and fulfilled by special trained service technicians.

- **General Safety and Effectiveness Concerns:**

The device labelling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize hazards, Siemens adheres to recognized and established industry practice and standards.

- **Substantial Equivalence:**

The *syngo*.via WebViewer, addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

Manufacturer	*Predicate Device Name*	*FDA Clearance Number*
Siemens	*syngo*.x	K092519
Siemens	*InSpace 4D*	K062673

The *syngo*.via WebViewer described in this 510(k) has similar intended use and similar technical characteristics as the devices listed above in regard to the specific functionalities.

Functionality	*Syngo* WebViewer
Manufacturer	identical
Intended use	identical to meaning of *syngo.x*
Image communication	Subset of *syngo*.x , Subset of InSpace 4D
Image Processing and Evaluation	Identical to InSpace 4D, Subset of *syngo*.x
Supported Image Types	Superset of InSpace 4D, Subset of *syngo*.x
Image data compression	Identical to syngo.x, Similar to InSpace 4D
User administration	identical
User Interface	Identical to InSpace 4D, Similar to *syngo*.x
Hardware	similar to InSpace 4D, Similar to *syngo*.x

The device was designed according to the QSR compliant design process and passed all necessary verification and validation steps to demonstrate safety and effectiveness.

All software lifecycle aspects are done according to IEC 62304. Safety and hazard considerations are performed according to ISO 14971 and IEC 60601-1-4.

Usability aspects are implemented, verified and validated according to IEC 60601-1-1-6.

Communication with connected medical devices is done via DICOM and HL7 where appropriate.

To ensure proper image quality compression is done according to ISO 109019-1 (JPEG) and ISO 154444-1 (JPEG2000). Furthermore SMPTE Pattern according SMPTE: 1995 is used for verification and validation activities.

In summary, Siemens is of the opinion that *syngo*.via WebViewer does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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NEW BRIGHTON MN 55112-1891

MAY 13 2011

Re: K111079
Trade/Device Name: *syngo*®, via WebViewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 13, 2011
Received: April 18, 2011

Dear Mr. Stuiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: *syngo*®.via WebViewer

Indications For Use:

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Prescription Use X AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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